K061700 10/26/06



**510(k) Summary**

General Information

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|---|---|
| Classification | Class II, Surgical Staple per 21 CFR § 878.4750 |
| Trade Name | NeoTract Anchor (REF 10230-01) |
| Submitter | NeoTract, Inc.<br>4473 Willow Road, Suite 100<br>Pleasanton, CA 34588<br><br>Tel. 415 609 9875 |
| Contact | Kevin F. MacDonald<br>Regulatory Consultant |

Intended Use

The NeoTract Anchor is intended for the approximation of tissue in open surgical procedures.

Predicate Devices

Onux Salute Stapler and Staples - K003522
(Davol® Salute® Fixation System)

Device Description

The NeoTract Anchor is designed to approximate tissue following open surgical procedures.

Materials

The materials used in the manufacture of the NeoTract Anchor are well-characterized implant materials and are suitable for this use. The materials have been used in previously cleared products.

Testing Summary

Simulated use and performance testing was conducted on the NeoTract Anchor and compared to the predicate device, Onux Salute (Davol® Salute® Fixation System). All components, subassemblies, and/or full devices met the required specifications for the completed tests. The NeoTract Anchor was designed under the NeoTract Quality System that is in compliance with 21CFR§820.30.

Summary of Substantial Equivalence

The NeoTract Anchor is substantially equivalent to the predicate device, the Onux Salute (Davol® Salute® Fixation System). The indications for use, function, methods of manufacturing, and materials used are substantially equivalent. NeoTract, Inc. believes the NeoTract Anchor is substantially equivalent to existing legally marketed devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 26 2006

NeoTract, Inc.
% Mr. Kevin F. MacDonald
Clinical/Regulatory Consultant
4473 Willow Road, Suite 100
Pleasanton, California 94588

Re: K061700
Trade/Device Name: NeoTract Anchor (REF 10230-01)
Regulation Number: 21 CFR 878.5010
Regulation Name: Nonabsorbable polypropylene surgical suture
Regulatory Class: II
Product Code: GAW, GDW
Dated: October 11, 2006
Received: October 12, 2006

Dear Mr. MacDonald:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Indications for Use

510(k) Number (if known): K061700

Device Name: NeoTract Anchor (REF 10230-01)

Indications for Use: The NeoTract Anchor is intended for the approximation of soft tissue in open surgical procedures.

Prescription Use ___X___ OR Over-The-Counter Use_____

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Per 21 CFR 801.109) (Optional Format 1-2-96)